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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FALK, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,243

Applicant(s)

KIRSCHBAUM ET AL.

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 September 2004 and 04 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1632

DETAILED ACTION

The amendment filed September 21, 2004 has been entered. The remarks filed June 4, 2004 (herein referred to as "the response") are considered herein. The amendment to the specification filed June 4, 2004 has been entered. Claims 7-10 have been amended.

Accordingly, Claims 1-35 and 37 remain pending in the instant application.

The priority issue has been overcome in view of the amendment to the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amended claim includes new matter.

Claim 10 is directed to the method of Claim 7, wherein said transgene is introduced into said cells by introducing said transgene into a stem cell that is combined with a blastocyst of said non-human animal. The claim has been amended to recite the new limitation referring to "a stem cell that is combined with a blastocyst." However, the specification does not appear to describe a stem cell

Art Unit: 1632

combined with a blastocyst. Applicants have not pointed to support in the as-filed specification and the Examiner does not find support for the new claim limitation.

Thus, the amended claims include new matter.

Enablement

Claims 1-35 and 37 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 3-8 of the Office Action mailed 12/4/03, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At page 8 of the response, Applicants assert that they are now providing the figures that are referred to in the Declaration of Dr. Kirschbaum. However, as stated in the prior Office Action at page 7, paragraph 2, the Declaration does not describe the protocols that were used for isolating the various complexes. Without this information the Examiner cannot determine if the isolation protocols were carried out in accordance with the teachings of the specification. The Declaration has been fully considered but is not found persuasive due to the deficiency noted.

Thus, the rejection under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-10 are indefinite in their recitation of "introducing said transgene into an embryonic cell of said non-human animal" and "transferring said transfected embryonic cell to a surrogate mother, and permitting said cell to develop into a non-human transgenic animal" because a "an embryonic cell"

Art Unit: 1632

cannot develop into an animal; only an embryo can develop into an animal. Claim 10 recites introducing the transgene into a “stem cell that is combined with a blastocyst”, but only an embryonic stem cell can be combined with a blastocyst to produce (develop into) an animal upon transfer to a surrogate mother. The term “stem cell” is very broad, covering neural stem cells, hematopoietic stem cells, and a wide variety of other stem cell types, most of which cannot be used to produce a transgenic animal. Only an embryonic stem cell can be used to produce a transgenic animal. Likewise, a blastomere (as recited in Claim 9) cannot develop into an animal upon transfer to a surrogate mother. The claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

At page 9 of the response, Applicants assert that the amendments to the claims obviate the indefiniteness rejection. On the contrary, for the reasons detailed above, the claims remain indefinite.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

A handwritten signature in black ink that reads "Anne-Marie Falk". The signature is written in a cursive, flowing style.

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER